Project BioShield: Authorities, Appropriations, Acquisitions, and Issues for Congress

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June 23, 2010

Congressional Research Service
7-5700
www.crs.gov
R41033

CRS Report for Congress
Prepared for Members and Committees of Congress

Report Documentation Page					*Form Approved* *OMB No. 0704-0188*
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1. REPORT DATE **23 JUN 2010**	2. REPORT TYPE				3. DATES COVERED **00-00-2010 to 00-00-2010**
4. TITLE AND SUBTITLE **Project BioShield: Authorities, Appropriations, Acquisitions, and Issues for Congress**					5a. CONTRACT NUMBER
					5b. GRANT NUMBER
					5c. PROGRAM ELEMENT NUMBER
6. AUTHOR(S)					5d. PROJECT NUMBER
					5e. TASK NUMBER
					5f. WORK UNIT NUMBER
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) **Congressional Research Service,Library of Congress,101 Independence Ave., SE,Washington,DC,20540-7500**					8. PERFORMING ORGANIZATION REPORT NUMBER
9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)					10. SPONSOR/MONITOR'S ACRONYM(S)
					11. SPONSOR/MONITOR'S REPORT NUMBER(S)
12. DISTRIBUTION/AVAILABILITY STATEMENT **Approved for public release; distribution unlimited**					
13. SUPPLEMENTARY NOTES					
14. ABSTRACT					
15. SUBJECT TERMS					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT **unclassified**	b. ABSTRACT **unclassified**	c. THIS PAGE **unclassified**	**Same as Report (SAR)**	**17**	

Standard Form 298 (Rev. 8-98)
Prescribed by ANSI Std Z39-18

Summary

Many potential chemical, biological, radiological, and nuclear (CBRN) terrorism agents lack available medical countermeasures. In 2003, President Bush proposed Project BioShield to address this need. The Project BioShield Act became law in July 2004 (P.L. 108-276).

This law has three main provisions: (1) relaxing regulatory requirements for some CBRN terrorism-related spending, including hiring personnel and awarding research grants; (2) guaranteeing a federal government market for new CBRN medical countermeasures; and (3) permitting emergency use of unapproved countermeasures. The Department of Health and Human Services (HHS) has used each of these authorities. The HHS used expedited review authorities to approve contracts and grants related to CBRN countermeasure research and development. The HHS used the authority to guarantee a government market to obligate approximately $2 billion to acquire countermeasures against anthrax, botulism, radiation, and smallpox. The HHS has also employed the emergency use authority several times, including allowing young children with H1N1 "swine" influenza to receive specific antiviral drugs.

The Department of Homeland Security (DHS) Appropriations Act, 2004 (P.L. 108-90) advance-appropriated $5.593 billion for FY2004 to FY2013 for CBRN countermeasures acquisition through Project BioShield. Subsequent Congresses have rescinded or transferred to other accounts approximately 19% of the advance appropriation. In FY2004 and FY2005, Congress removed a total of approximately $25 million from this account through rescissions included in the Consolidated Appropriations Act, 2004 (P.L. 108-199) and the Consolidated Appropriations Act, 2005 (P.L. 108-447). In the Omnibus Appropriations Act, 2009 (P.L. 111-8), Congress transferred $412 million from this account to support countermeasure advanced research and development and pandemic influenza preparedness and response. The Consolidated Appropriations Act, 2010 (P.L. 111-117) transferred $609 million from this account to support basic research and advanced countermeasure development. P.L. 111-117 also transferred the remaining Project BioShield funds from DHS to HHS. For FY2011, President Obama has requested the transfer of at least $476 million from this account to support countermeasure advanced development.

Since passing the Project BioShield Act, subsequent Congresses have considered additional measures to further encourage countermeasure development. The 109th Congress passed the Pandemic and All-Hazard Preparedness Act (P.L. 109-417) which created the Biomedical Advanced Research and Development Authority (BARDA) in HHS. Amongst other duties, BARDA oversees all of HHS' Project BioShield activities. The Pandemic and All-Hazard Preparedness Act also modified the Project BioShield procurement process. Some stakeholders question whether these changes have sufficiently improved countermeasure development and procurement. The Administration is considering implementing additional changes to the countermeasure research, development, and acquisition process.

The 111th Congress continues to address several Project BioShield-related policy issues. These include whether to continue diverting Project BioShield acquisition funding to other purposes; whether to change the countermeasure development and acquisition process; how to replace stockpiled countermeasures as they expire; and whether to alter federal efforts to encourage the development of broad-spectrum countermeasures.

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Introduction

Following the terrorist attacks of 2001, the federal government determined that it would need new medical countermeasures (such as diagnostic tests, drugs, vaccines, and other treatments) to respond to an attack using chemical, biological, radiological, or nuclear (CBRN) agents. Representatives of the pharmaceutical industry attributed the paucity of CBRN agent countermeasures to the lack of a significant commercial market.[1] They argued that because these diseases and conditions occur infrequently, the private sector perceived little economic incentive to invest the millions of dollars required to bring treatments to market.

In 2004, Congress passed the Project BioShield Act (P.L. 108-276) to encourage the development of CBRN medical countermeasures. The 108th Congress also appropriated $5.6 billion to acquire countermeasures through Project BioShield for FY2004 through FY2013. Subsequent congresses have evaluated implementation of Project BioShield. In response to perceived problems with Project BioShield countermeasure procurement, the 109th Congress created the Biodefense Advanced Research and Development Authority (BARDA) and the position of Assistant Secretary for Preparedness and Response in the Department of Health and Human Services (HHS) through the Pandemic and All-Hazards Preparedness Act (P.L. 109-417).

The 111th Congress continues to address several Project BioShield-related policy issues. These include whether to continue diverting Project BioShield acquisition funding to other purposes; whether to change the countermeasure development and acquisition process; how to replace stockpiled countermeasures as they expire; and whether to alter federal efforts to encourage the development of broad-spectrum countermeasures.

The Project BioShield Act

To encourage the development of new CBRN countermeasures, President Bush proposed Project BioShield in his 2003 State of the Union address. The 108th Congress considered this proposal and passed the Project BioShield Act of 2004 (P.L. 108-276, signed into law July 21, 2004).[2] It has three main provisions. The first provision provides HHS expedited procedures for CBRN terrorism-related spending, including procuring products, hiring experts, and awarding research grants. The second provision creates a government-market guarantee by permitting the HHS Secretary to obligate funds to purchase countermeasures while they still need several more years of development. The third provision authorizes the HHS Secretary to temporarily allow the emergency use of countermeasures that lack Food and Drug Administration (FDA) approval.

Expedited Procedures

The act relaxes Federal Acquisition Regulation procedures HHS must follow when procuring property or services used in performing, administering, or supporting CBRN countermeasure

[1] For example, Alan Pemberton, Pharmaceutical Research and Manufacturers of America, Testimony before the U.S. House of Representatives Select Committee on Homeland Security, May 15, 2003.

[2] For legislative history of this law, see CRS Report RL32549, *Project BioShield: Legislative History and Side-by-Side Comparison of H.R. 2122, S. 15, and S. 1504*, by Frank Gottron and Eric A. Fischer.

research and development (R&D). These expedited procedures decrease both the amount of paperwork required for these expenditures and the potential for oversight. The act also increases the maximum amount, from $100 thousand to $25 million, for contracts awarded under simplified acquisition procedures. It also allows these purchases using other than full and open competition. According to the Government Accountability Office (GAO), HHS used the simplified acquisitions procedure authority for five contracts. These contracts, all executed between 2004 and 2005 using funds from the National Institutes of Health, totaled approximately $30 million.[3] Through December 2008, HHS had not exercised its authority to use other than full and open competition.[4]

The Project BioShield Act authorizes the HHS Secretary to use an expedited award process for grants, contracts, and cooperative agreements related to CBRN countermeasure R&D, if the Secretary deems that a pressing need for an expedited award exists. The act limits this authority to awards worth $1.5 million or less. This expedited award process replaces the normal peer review process. Some scientists have expressed concerns that an expedited review process would reduce research quality.[5] The normal peer review process can provide proposals with greater scientific merit a higher probability of receiving funding, a factor potentially lost in an expedited process. According to HHS, the National Institute of Allergies and Infectious Diseases (NIAID) awarded 5 contracts and 47 grants through this expedited peer review process through December 2008.[6] The NIAID awarded these expedited grants within three to nine months after the application deadline. Grants that go through the normal peer review process typically take 9 to 18 months to receive funding.[7]

Market Guarantee

The Project BioShield Act is designed to guarantee companies that the government will buy new, successfully developed CBRN countermeasures for the Strategic National Stockpile (SNS).[8] The act allows the HHS Secretary, with the concurrence of the DHS Secretary and upon the approval of the President, to promise to buy a product up to eight years before it is reasonably expected to be delivered.[9] Originally, HHS could pay a company only on the delivery of a substantial portion

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[3] These contracts are distinct from the contracts using Project BioShield funds described later in this report (see "Acquisitions"). The HHS used these contracts to purchase treatments for botulism and internal radioactive particle contamination. See U.S. Government Accountability Office, *Project BioShield: HHS Can Improve Agency Internal Controls for Its New Contracting Authorities*, GAO-09-820, July 21, 2009, p. 7.

[4] U.S. Government Accountability Office, *Project BioShield: HHS Can Improve Agency Internal Controls for Its New Contracting Authorities*, GAO-09-820, July 21, 2009, http://www.gao.gov/new.items/d09820.pdf; U.S. Department of Health and Human Services, *Project BioShield Annual Report to Congress August 2007 through December 2008*, 2009, p. 8.

[5] John Miller, "Interview with Richard Ebright," *The Scientist*, vol. 17 (7), April 7, 2003, p. 52.

[6] The HHS has not published 2009 data as of the appearance of this report in June 2010. See U.S. Department of Health and Human Services, *Project BioShield Annual Report to Congress July 2004 -July 2006*, p. 2; U.S. Department of Health and Human Services, *Project BioShield Annual Report to Congress August 2006 -July 2007*, p. 32; and U.S. Department of Health and Human Services, *Project BioShield Annual Report to Congress August 2007 through December 2008*, p. 9.

[7] See http://www.niaid.nih.gov/ncn/grants/charts/timeline_resub.htm.

[8] The SNS contains pharmaceuticals, vaccines, medical supplies, and medical equipment to respond to terrorist attacks and other emergencies.

[9] President Bush delegated the presidential approval step to the Director of the Office of Management and Budget (OMB). The OMB retains this authority in the Obama administration. See Executive Office of the President, "Designation and Authorization to Perform Functions under Section 319F-2 of the Public Health Service Act," 69 *Fed.* (continued...)

of the countermeasure. The Pandemic and All-Hazard Preparedness Act (P.L. 109-417) modified the Project BioShield Act to allow for milestone-based payments of up to half of the total award before delivery.[10] Therefore, this guarantee reduces the market risk for the company and the milestone payments partially reduce the company's exposure to development risk (i.e., the risk that the countermeasure will fail during testing and be undeliverable).

The Project BioShield Act allows HHS to purchase unapproved and unlicensed countermeasures. It requires the HHS Secretary to determine that "sufficient and satisfactory clinical experience or research data ... support[s] a reasonable conclusion that the product will qualify for [FDA] approval or [HHS] licensing ... within eight years."[11] Because most drugs that begin these processes fail to become approved treatments, critics of this provision suggest that the government will end up purchasing countermeasures that may never be approved. To reduce the government's financial risk associated with this provision, the act allows HHS to write contracts in which unapproved products may be purchased at lower cost than approved products. The HHS used some of these authorities when structuring each of the Project BioShield contracts discussed below (see "Acquisitions" below).

Emergency Use of Unapproved Products

The FDA and HHS designed their approval and licensing processes to protect people from ineffective or dangerous treatments. The Project BioShield Act allows the HHS Secretary to temporarily authorize the emergency use of medical products that are not approved by the FDA or licensed by HHS. To exercise this authority, the HHS Secretary must conclude that:

- the agent for which the countermeasure is designed can cause serious or life-threatening disease;
- the product may reasonably be believed to be effective in detecting, diagnosing, treating, or preventing the disease;
- the known and potential benefits of the product outweigh its known and potential risks;
- no adequate alternative to the product is approved and available; and
- any other criteria prescribed in regulation are met.[12]

Such emergency use authorizations (EUAs) remain in effect for one year unless the Secretary terminates them earlier. The Secretary may renew expiring authorizations.

(...continued)

Reg. 70349, December 3, 2004.

[10] For more on this law, see CRS Report RL33589, *The Pandemic and All-Hazards Preparedness Act (P.L. 109-417): Provisions and Changes to Preexisting Law*, by Sarah A. Lister and Frank Gottron.

[11] 42 U.S.C. § 247d-6b(c).

[12] 21 U.S.C. § 360bbb-3(c). For more information on how the Secretary determines whether a product meets these conditions, see U.S. Department of Heath and Human Services, Food and Drug Administration, *Guidance—Emergency Use Authorization of Medical Products*, July 2007, available at http://www.fda.gov/RegulatoryInformation/Guidances/ucm125127.htm.

The HHS Secretary has issued several EUAs. In January 2005, the HHS Secretary issued an EUA allowing the vaccination of Department of Defense (DOD) personnel with a specified type of anthrax vaccine.[13] This EUA expired in January 2006. The HHS Secretary issued EUAs to permit use of five countermeasures to the 2009 H1N1 "swine" influenza outbreak:[14] the antiviral influenza treatments Tamiflu (oseltamivir) and Relenza (zananivir),[15] N95 respirators, and two diagnostic kits to help identify cases of this disease.[16] These EUAs expired June 23, 2010. The only EUA remaining active permits the distribution of antibiotic kits containing doxycycline hyclate to certain people participating in the Cities Readiness Initiative.[17]

Reporting Requirements

The Project BioShield Act of 2004 requires the HHS Secretary to report annually to Congress on the use of some of the authorities granted by this law. The reports must summarize each instance that HHS used the expedited procurement and grant procedures and allowed the emergency use of unapproved products. The reports must explain why HHS needed to use these authorities. The HHS has produced three such reports to date.[18]

This act also requires GAO to assess actions taken under authorities granted by the act, determine the effectiveness of the act, and recommend additional measures to address deficiencies. In July 2009, GAO published two reports in response to this requirement. The first report recommended that HHS improve some internal controls it implemented for the expedited contracting procedures (see "Expedited Procedures" above).[19] The second report described the manner in which HHS had used Project BioShield to support development and procurement of CBRN medical countermeasures.[20] This report contained no recommendations for improving Project BioShield.[21]

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[13] 70 *Fed. Reg.* 5452.

[14] For additional information, see CRS Report R40554, *The 2009 Influenza Pandemic: An Overview*, by Sarah A. Lister and C. Stephen Redhead.

[15] Although the antiviral treatments had been previously approved for treating influenza, the EUA makes it easier to distribute these treatments and allows their use for infants and children younger than had been previously allowed.

[16] For more information on these EUAs, see http://www.cdc.gov/h1n1flu/eua/.

[17] For more on this program, see http://www.bt.cdc.gov/cri/. Absent further action, this EUA will expire on October 1, 2010.

[18] Available online at http://www.hhs.gov/aspr/barda/bioshield/annualreport/.

[19] U.S. Government Accountability Office, *Project BioShield: HHS Can Improve Agency Internal Controls for Its New Contracting Authorities*, GAO-09-820, July 21, 2009, http://www.gao.gov/new.items/d09820.pdf.

[20] U.S. Government Accountability Office, *Project BioShield Act: HHS Has Supported Development, Procurement, and Emergency Use of Medical Countermeasures to Address Health Threats*, GAO-09-878R, July 24, 2009, http://www.gao.gov/new.items/d09693r.pdf.

[21] Other BioShield-related GAO reports include U.S. Government Accountability Office, *Anthrax: Federal Agencies Have Taken Some Steps to Validate Sampling Methods and to Develop a Next-Generation Anthrax Vaccine*, GAO-06-756T, May 9, 2006; and U.S. Government Accountability Office, *Project BioShield: Actions Needed to Avoid Repeating Past Problems with Procuring New Anthrax Vaccine and Managing the Stockpile of Licensed Vaccine*, GAO-08-88, October 23, 2007.

Appropriations

The Project BioShield Act did not appropriate any funds. Instead, it authorized the appropriation of up to a total of $5.593 billion for procuring countermeasures from FY2004 through FY2013. The Department of Homeland Security Appropriations Act, 2004 (P.L. 108-90) appropriated this amount into a special reserve fund and provided explicit time windows during which the money could be obligated. P.L. 108-90 specified that $3.418 billion were available for obligation from FY2004 to FY2008. The balance of the advance appropriation plus unobligated funds remaining from FY2004 to FY2008 became available in FY2009 for obligation from FY2009 to FY2013. The Project BioShield Act specified that these funds are only for the procurement of CBRN countermeasures using the Project BioShield authorities and may not be used for other purposes, such as countermeasure development grants or program administration.

Congress advance-appropriated the 10-year program but retains the power to annually increase or decrease the amount in the special reserve fund. Congress removed $25 million from this account through rescissions enacted in the Consolidated Appropriations Act, 2004 (P.L. 108-199) and the Consolidated Appropriations Act, 2005 (P.L. 108-447). See **Table 1**.

Congress has also transferred funds from this account for purposes other than CBRN countermeasure procurement. These transfers fall into two categories: those related to pandemic influenza preparedness and those related to CBRN countermeasures research and development. The Omnibus Appropriations Act, 2009 (P.L. 111-8) transferred $412 million to HHS from the special reserve fund. Of this amount, $137 million went to help respond to and prepare for pandemic influenza and $275 million went to fund countermeasure advanced development through the Biodefense Advanced Research and Development Authority (BARDA, see "BioShield and BARDA" below).[22] The Consolidated Appropriations Act, 2010 (P.L. 111-117) transferred $609 million to HHS. Of this amount, $305 million went to BARDA for countermeasure advanced development and $304 million went to the National Institute of Allergy and Infectious Diseases to fund countermeasure basic research. See **Table 1**.

Congress transferred the remaining balance in the DHS "Biodefense Countermeasure" account, into the HHS "Public Health and Social Services Emergency Fund" account through the Consolidated Appropriations Act, 2010 (P.L. 111-117). These funds are to remain available for obligation through FY2013 for Project BioShield-related countermeasure purchases. Congressional appropriators estimated that after accounting for the FY2010 transfers for basic research and advanced development, $2.424 billion remained available for Project BioShield acquisitions at the beginning of FY2010.[23]

In his FY2011 budget request, President Obama proposed spending at least $476 million of Project BioShield funds on BARDA activities, including to fund advanced development of CBRN countermeasures and BARDA's administrative costs.[24] The administration's proposal would also allow the HHS Secretary to transfer additional Project BioShield funds to support countermeasure

[22] P.L. 111-8 explanatory statement, *Congressional Record*, February 23, 2009, p. H2240.

[23] H.Rept. 111-366, p. 1045.

[24] U.S. Department of Health and Human Services, *FY2011 Public Health and Social Services Emergency Fund Justification of Estimates for Appropriations Committees*, p. 13.

development 15 days after notifying congressional appropriators. This requested authority has no explicit limit, i.e. all remaining Project BioShield funds would be eligible for such a transfer.

Table 1. Project BioShield Rescissions and Transfers: FY2001 to FY2011

(Actual and Proposed)

Fiscal Year	Public Law	Purpose	Amount ($ in millions)
2004	P.L. 108-199	Rescission	5
2005	P.L. 108-447	Rescission	20
2009	P.L. 111-8	Transfer for Advanced Development	275
		Transfer for Pandemic Flu Preparedness	137
2010	P.L. 111-117	Transfer for Advanced Development	305
		Transfer for Basic Research	304
2011	President's Budget Request	Transfer for Advanced Development and Administration	476[a]
		Total Actual and Proposed Rescissions and Transfers	1,522

Source: CRS analysis of P.L. 108-199; P.L. 108-447; P.L. 111-8; P.L. 111-117; and HHS, *FY2011 Public Health and Social Services Emergency Fund Justification of Estimates for Appropriations Committees*.

Note: Amounts rounded to nearest million.

a. The request would also allow the HHS Secretary to increase this transfer amount 15 days after notifying the House and Senate appropriation committees.

Acquisitions

The first Project BioShield contract was announced on November 4, 2004.[25] The HHS contracted with VaxGen, Inc. for delivery of 75 million doses of a new type of anthrax vaccine (recombinant protective antigen or rPA) within three years. This contract had a value of $879 million. See **Table 2**. On December 17, 2006, HHS terminated this contract because VaxGen, Inc., failed to meet a contract milestone.[26] Subsequent contracts include:

- $690 million for 29 million doses of the currently approved anthrax vaccine (anthrax vaccine adsorbed or AVA) from Emergent BioSolutions, Inc.;
- $315 million for 65 thousand doses of Raxibacumab (ABthrax), a treatment for anthrax, from Human Genome Sciences, Inc.;
- $144 million for 10 thousand doses of Anthrax Immune Globulin, a treatment for anthrax, from Cangene Corporation;

[25] For the status of current requests and contracts, see the U.S. Department of Health and Human Services Project BioShield procurement page at http://www.hhs.gov/aspr/barda/procurement/cbrnactivities.html. For issues regarding these awards, see CRS Report RL33907, *Project BioShield: Appropriations, Acquisitions, and Policy Implementation Issues for Congress*, by Frank Gottron.

[26] U.S. Department of Health and Human Services, "Termination Letter - Contract No. HHSO100200500001C," Letter to VaxGen, Inc., December 19, 2006.

- $505 million for 20 million doses of a new smallpox vaccine (Modified Vaccinia Ankara or MVA) from Bavarian Nordic, Inc.;
- $416 million for 200 thousand doses of botulinum antitoxin, a treatment for botulinum toxin exposure, from Cangene Corporation;
- $18 million for 5 million doses of a pediatric form of potassium iodide, a treatment for radioactive iodine exposure, from Fleming Pharmaceuticals; and
- $22 million for 395 thousand doses of pentetate calcium trisodium (also known as Ca-DTPA) and 80 thousand doses of pentetate zinc trisodium (also known as Zn-DTPA), two treatments for internal radioactive particle contamination, from Akorn, Inc.

Thus, excluding the canceled VaxGen contract, HHS has obligated approximately $2.111 billion to date. Future targets for Project BioShield procurement include countermeasures against anthrax, viral hemorrhagic fevers, and radiation.[27]

[27] U.S. Department of Health and Human Services, Public Health Emergency Medical Countermeasure Enterprise, "Implementation Plan for Chemical, Biological, Radiological and Nuclear Threats," 72 *Fed. Reg.* 20122, April 23, 2007.

Table 2. Project BioShield Acquisition Activity

Threat	Product	Doses (thousands)	Cost ($ millions)	Company	Award Date
Anthrax	rPA vaccine	75,000	879[a]	VaxGen, Inc.	11/4/04; Cancelled 12/19/06
	AVA vaccine	28,750	690[b]	Emergent BioSolutions, Inc. (formerly BioPort Corp.)	5/6/05; 5/5/06; 9/25/07
	Raxibacumab	65	315	Human Genome Sciences, Inc.	6/19/06; 7/29/2009
	Anthrax Immune Globulin	10	144	Cangene Corp.	7/28/06
Smallpox	MVA vaccine	20,000	505	Bavarian Nordic, Inc.	6/4/07
Botulinum Toxin	Botulinum Antitoxin	200	416[c]	Cangene Corp.	6/1/06
Radiological/ Nuclear	Potassium Iodide	4,800	18	Fleming Pharmaceuticals	3/18/05 and 2/8/06
	Ca-DTPA Zn-DTPA	395 80	22	Akorn, Inc.	2/13/06
Total Announced Obligations:			**2,989**		
Total Active Announced Obligations:			**2,111**[d]		

Source: CRS analysis of HHS, *Project BioShield: Annual Report to Congress July 2004 -July 2006*; HHS, *Project BioShield: Annual Report to Congress August 2006 -July 2007*; HHS, *Project BioShield Annual Report to Congress August 2007 through December 2008;* HHS, "CBRN Acquisition Activities" http://www.hhs.gov/aspr/barda/procurement/cbrnactivities.html; DHS, Office of Health Affairs*, Biodefense Countermeasures Congressional Justification FY2010*; and personal communication with HHS, June 8, 2009.

a. This figure includes approximately $1.5 million that HHS paid to VaxGen, Inc. for mandatory security upgrades. When HHS terminated the vaccine contract, VaxGen, Inc. kept this amount, while approximately $878 million obligated for the vaccine became available for other Project BioShield procurements. Personal communication with BARDA, June 8, 2009.

b. This total does not include a $405 million contract for 14.5 million doses of AVA anthrax vaccine that HHS announced on September 30, 2008. According to HHS, this contract used Centers for Disease Control and Prevention funds rather than the Project BioShield special reserve fund. Personal communication with HHS, June 8, 2009.

c. This figure includes $50 million HHS obligated from the Project BioShield special reserve fund to this company in FY2004 after the DHS Appropriations Act, 2004, funded this account but before passage of the Project BioShield Act. See HHS, *Project BioShield: Annual Report to Congress July 2004—July 2006*, January 2007, p. 31.

d. Announced obligations minus $878 million for the cancelled rPA contract (see note a).

BioShield and BARDA

Congressional policymakers have scrutinized the implementation and effectiveness of the Project BioShield Act since its enactment. In response to perceived problems with Project BioShield countermeasure procurement, the 109th Congress, in the Pandemic and All-Hazards Preparedness Act (P.L. 109-417), created the Biodefense Advanced Research and Development Authority (BARDA) in HHS.

Many congressional policymakers concluded that Project BioShield had insufficiently encouraged the transition of promising basic research results into the product development stage. This period is often referred to as the "valley of death" because some seemingly promising products are not developed past this point due to lack of funding. As discussed above, Congress amended the Project BioShield Act through the Pandemic and All-Hazards Preparedness Act to allow HHS to pay up to half a Project BioShield contract's value in a series of sequential milestone payments. Thus, companies could receive payments while continuing to develop their promising product. Additionally, Congress created in BARDA a dedicated infrastructure to manage and fund advanced development and commercialization of CBRN countermeasures. In theory, industry can use BARDA funding to take promising drugs from the basic research through the advanced development stage, which may include clinical trials. Congress created the Biodefense Medical Countermeasure Development Fund to pay for such advanced development contracts. Although this account is separate from the Project BioShield special reserve fund, Congress has repeatedly funded the advanced development account through transfers from the Project BioShield account (see **Table 1**).

Critics of government funding for advanced development suggest that because of the high product failure rate, the government will inevitably fund unusable products. In addition to removing the development risks traditionally borne by industry, critics argue, directly funding advanced development inserts government decision-makers into the countermeasure development process; a role better suited to industry experts and entrepreneurs.[28] Some critics would prefer to have the government set product requirements and have industry determine how best to meet them. As originally enacted, Project BioShield took this latter approach, which Congress found insufficient in this particular case. Because advanced development activities can be lengthy, it may take several years to determine if this change has yielded better results than the original Project BioShield.

In addition to funding the advanced development of countermeasures, BARDA manages HHS' role in Project BioShield. The BARDA leads efforts to determine countermeasure requirements and executes all Project BioShield contracts.

Policy Issues

The 111th Congress continues to address several Project BioShield-related policy issues. These include whether to continue diverting Project BioShield acquisition funding to other purposes; whether to change the countermeasure development and acquisition process; how to replace

[28] For more on these claims, see CRS Report RL33528, *Industrial Competitiveness and Technological Advancement: Debate Over Government Policy*, by Wendy H. Schacht.

stockpiled countermeasures as they expire; and whether to alter federal efforts to encourage the development of broad-spectrum countermeasures.

Diversion of BioShield Funds to Other Purposes

One of the distinguishing features of Project BioShield is the ten-year $5.6 billion advance appropriation. Potential countermeasure developers considered the establishment of an advance-funded separate account dedicated solely to countermeasure procurement as integral to their participation in this program. The advance funding helped assure developers that payment for countermeasures they successfully developed would not depend on future, potentially uncertain appropriations processes. Although advance-funding the Project BioShield account may have provided some assurance of stability to developers, in practice, these funds have been subject to the annual appropriations process. Subsequent Congresses have rescinded or transferred approximately 19% of the advance appropriation and the Administration has requested additional diversions for FY2011. See **Table 1**. These transfers fall into two categories: those related to CBRN countermeasures research and development and those related to pandemic influenza preparedness.

In appropriating $5.6 billion over ten years for Project BioShield, Congress anticipated an average obligation rate of $560 million per each year. However, HHS has obligated at a slower pace. Had the transfers to other accounts not been made, HHS would need to obligate approximately $1.16 billion annually from FY2011 to FY2013 to exhaust the fund before its expiration. After accounting for the transfers, including the proposed FY2011 transfer, HHS could obligate $609 million annually for the remainder of the authorization period—a rate that still exceeds the rate HHS has been able to sustain since the inception of Project BioShield. Thus, the transfers out of this account could be interpreted as Congress and the President adjusting the amount of funds available so that they track more closely with the actual ability of HHS to obligate them.

Transfers for CBRN Countermeasure Research and Development

In FY2009 and FY2010, Congress transferred a total of $580 million from the special reserve fund to BARDA to support CBRN countermeasure advanced research and development. The Administration justified its requests for such transfers by asserting that these funds will support "future successful acquisitions of medical countermeasures under Project BioShield."[29] Thus, Congress could view such transfers as an attempt to improve the "lower than expected" rate of Project BioShield acquisitions.[30] In FY2010, citing similar reasons, Congress also transferred $304 million to NIAID for countermeasure basic research.[31] For FY2011, President Obama has requested transferring at least $476 million to fund countermeasure development and administrative costs in BARDA.

[29] U.S. Department of Health and Human Services, *FY2010 Congressional Justification for the Public Health and Social Services Emergency Fund*, p. 46.

[30] U.S. Department of Homeland Security, Office of Health Affairs, *Biodefense Countermeasures Congressional Justification FY2010*, p. BIO-2.

[31] H.Rept. 111-220, p. 194.

This pattern of annual transfers from the Project BioShield special reserve fund to support countermeasure research and development activities may affect future CBRN countermeasure development and procurement activities. Continued transfers would reduce the amount of money available for countermeasure procurement, could affect the willingness of developers to participate in Project BioShield, and might change the respective roles of federal government and private developers in countermeasure development.

Annual transfers from this account to fund countermeasure research and development would continue to lower the amounts available for procuring CBRN countermeasures, their originally intended purpose. However, if funding began to constrain countermeasure procurement, Congress could reverse this course and appropriate additional money for Project BioShield acquisitions.[32]

By providing ten-year advance funding, Congress attempted to assure countermeasure developers that the funding of this program was not subject to the annual appropriations process. Continuing the pattern of annual transfers out of this fund, even with the potential for additional appropriations in future years, might cause potential countermeasure developers to feel dependent on the actions of future appropriators, precisely the situation that establishment and advance funding of the special reserve fund was designed to ameliorate. If potential countermeasure developers feel more dependent on the actions of future appropriators, they may be less inclined to begin or continue countermeasure development.

Industry representatives reportedly have asserted that transferring money from this account weakens the ability of private firms to raise the capital necessary to sustain long-term research and development for countermeasures and hinders their potential participation in Project BioShield.[33] On the other hand, transferring funds to support advanced development may reduce the amount that developers need to raise from other sources.

Funding transfers may also modify the relative roles of the federal government and the private sector in Project BioShield. Congress originally designed Project BioShield to minimize the risk that the government would pay for countermeasures that fail during development (see "Market Guarantee" above). Congress expected developers to manage this risk, using the government-market guarantee to entice investors to fund countermeasure development. However, in using Project BioShield transfers to fund countermeasure development directly, the government assumes more of the development risk.

Transfer for Pandemic Influenza Preparedness

In FY2009, Congress transferred $137 million from the Project BioShield special reserve fund to HHS for pandemic influenza preparedness and response. Additionally, President Obama requested that the conference committee on the Supplemental Appropriations Act, 2009 (P.L. 111-32) allow the purchase of influenza countermeasures using the Project BioShield special reserve fund.[34] Critics of this move charged that it would damage the biodefense countermeasure industry, "severely diminish the nation's efforts to prepare for WMD events," and "will leave the

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[32] The House Committee on Appropriations has suggested that it would consider adding additional funds to the special reserve fund in the future. See H.Rept. 111-220, p. 194.

[33] Spencer Hsu, "Bipartisan WMD Panel Criticizes Obama Plan To Fund Flu Vaccine," *Washington Post*, June 8, 2009.

[34] Letter from President Barack Obama to Speaker of the House Nancy Pelosi, June 2, 2009, http://www.whitehouse.gov/omb/assets/budget_amendments/supplemental_06_02_09.pdf.

nation less, not more, prepared."[35] The conferees declined to provide this authority.[36] Similarly, in the Senate report to accompany the Department of Homeland Security Appropriations Act, 2010 (S. 1298), the committee "strongly" urged not using the special reserve fund to purchase influenza countermeasures.[37] President Obama did not request similar pandemic influenza preparedness related transfers for FY2010 or FY2011.

Changing the Countermeasure Development and Acquisition Process

Project BioShield represents just one piece of the federal effort to research, develop, and acquire countermeasures for civilian use. Other important aspects of this effort include risk assessment, strategic planning, countermeasure prioritization, basic research, countermeasure approval, and countermeasure distribution. Various federal agencies and departments have roles in different parts of this effort.[38] Experts inside and outside government have concluded that better coordination and stronger management of the overall process would increase the pace of countermeasure development and acquisition.[39]

HHS Secretary Sebelius ordered a comprehensive review of how her department develops and acquires countermeasures to all public health threats, including CBRN agents.[40] As part of this review, the Institute of Medicine and the National Biodefense Science Board have examined these issues. Their independent recommendations include empowering a single office to have the authority and responsibility to align component agencies' efforts; developing a coordinated budget request for HHS and DOD agencies involved in countermeasure development, approval, and acquisition; developing a common set of prioritized product needs and research dispensing goals to support them; and increasing the funding available for countermeasure acquisition and advanced development.[41]

[35] Letter from Senator Bob Graham, Chairman of the Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism, and Senator Jim Talent, Vice Chairman of the Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism, to President Obama, June 8, 2009, http://www.preventwmd.gov/6_8_2009/; Spencer Hsu, "Bipartisan WMD Panel Criticizes Obama Plan To Fund Flu Vaccine," *Washington Post*, June 8, 2009; and Matt Korade, "Lawmakers, Industry Jeer Plan to Fund Flu Preparedness With Bioshield Money," *CQ Homeland Security*, June 9, 2009.

[36] P.L. 111-32 and H.Rept. 111-151.

[37] S.Rept. 111-31, p. 96.

[38] For additional information, see CRS Report R41123, *Federal Efforts to Address the Threat of Bioterrorism: Selected Issues for Congress*, by Frank Gottron and Dana A. Shea.

[39] For example, George Korch, Senior Science Advisor, U.S. Department of Health and Human Services Office of the Assistant Secretary for Preparedness and Response, "Increasing the Product Pipeline for the Public Health Emergency Medical Countermeasure Enterprise," White Paper for the Institute of Medicine Workshop, *The Public Health Emergency Medical Countermeasures Enterprise: Innovative Strategies to Enhance Products from Discovery Through Approval*, Washington, DC, February 22, 2010; and National Biodefense Science Board, *Where Are the Countermeasures? Protecting America's Health from CBRN Threats*, March 2010.

[40] Secretary of Health and Human Services Kathleen Sebelius, remarks to The American Medical Association Third National Congress on Health System Readiness, Washington, DC, December 1, 2009.

[41] Institute of Medicine Board on Health Sciences Policy, *The Public Health Emergency Medical Countermeasures Enterprise Innovative Strategies to Enhance Products from Discovery Through Approval: Workshop Summary*, National Academies Press, 2010; and National Biodefense Science Board, *Where Are the Countermeasures? Protecting America's Health from CBRN Threats*, March 2010.

Any changes that HHS proposes will likely draw congressional interest. Project BioShield was passed to increase delivery of CBRN countermeasures to the national stockpile. Both the Executive Branch and Congress have tried to improve how the overall process works. The Executive Branch created the Public Health and Emergency Medical Countermeasure Enterprise (PHEMCE) and promulgated a PHEMCE strategic plan and implementation plan.[42] As previously discussed, Congress created BARDA and the Office of the Assistant Secretary for Preparedness and Response (ASPR) through P.L. 109-417 in part to improve management and accountability of countermeasure procurement. Congress may take an interest in any proposed changes to the roles that it assigned BARDA or ASPR. Additionally, congressional policymakers will likely scrutinize the proposed changes to determine whether they will increase the successful development and acquisition of CBRN countermeasures for the national stockpile.

Stockpile Management

All medicines, including those added to the Strategic National Stockpile (SNS) through Project BioShield, have explicit expiration dates. The federal government does not allow the use of expired medicines. Countermeasure expiration raises at least two stockpile management issues: what to do with expiring countermeasures and how to replace them.

In 2007, the GAO suggested that HHS and DOD establish an inventory-sharing agreement. The agreement would allow DOD to use HHS-stockpiled vaccine in its anthrax vaccination program before expiration.[43] These agencies subsequently implemented a shared stockpile approach for both anthrax vaccines and pandemic influenza countermeasures.[44] However, this shared stockpile solution only applies to countermeasures having high-volume users. For other countermeasures such as smallpox vaccine, HHS may have to discard expired countermeasures and replace them without compensation.

Additionally, HHS must procure for the SNS a number of doses greater than that stored at any given time. For example, HHS had to buy 29 million doses of anthrax vaccine to maintain a stockpile of at least 10 million doses from 2006 to 2011.[45] HHS may require additional periodic countermeasure purchases to maintain a consistent readiness level and replenish the stockpile as the countermeasures expire. Congress may consider whether such purchases should be funded through the advance-appropriated Project BioShield account or through annual SNS appropriations. Between 2005 and 2007, BARDA purchased the AVA anthrax vaccine using

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[42] U.S. Department of Health and Human Services Public Health Emergency Medical Countermeasure Enterprise, "Strategy for Chemical, Biological, Radiological and Nuclear Threats," 72 *Fed. Reg.* 13109, March 20, 2007; and U.S. Department of Health and Human Services Public Health Emergency Medical Countermeasure Enterprise, "Implementation Plan for Chemical, Biological, Radiological and Nuclear Threats," 72 *Fed. Reg.* 20122, April 23, 2007.

[43] Government Accountability Office, *Project BioShield: Actions Needed to Avoid Repeating Past Problems with Procuring New Anthrax Vaccine and Managing the Stockpile of Licensed Vaccine*, GAO-08-88, October 2007.

[44] Robin Robinson, Deputy Assistant Secretary of Health and Human Services for Preparedness and Response, Testimony before the U.S. House of Representatives Committee on Appropriations, Subcommittee on Defense, April 24, 2008.

[45] U.S. Department of Health and Human Services, "HHS Purchases Additional Anthrax Vaccine for Stockpile," *News Release*, September 26, 2007.

Project BioShield funds (**Table 2**). However in 2008, HHS switched funding sources for this vaccine and used SNS funds to purchase additional doses of AVA vaccine.[46]

Broad-Spectrum Countermeasures

Many experts contend that broad-spectrum countermeasures, those that address multiple CBRN agents, would be the most valuable additions to the SNS.[47] Such nonspecific countermeasures might be a defense against currently unknown threats, such as emerging diseases or genetically engineered pathogens. Furthermore, such countermeasures are likely to have nonbiodefense-related applications as well. The Project BioShield Act does not exclude procuring such countermeasures; however, it does require that the presence of another commercial market be factored into the HHS Secretary's decision to purchase the countermeasure. The HHS has stated its interest in using Project BioShield to acquire new broad-spectrum countermeasures.[48] However, Project BioShield contracts to date have specifically targeted individual threat agents, a strategy commonly described as "one bug, one drug." Congress may decide that HHS needs further guidance or authorities to encourage the development and acquisition of new broad spectrum countermeasures.

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[46] Personal communication with U.S. Department of Health and Human Services staff, June 8, 2009.

[47] Some broad-spectrum treatments are available. For example, antibiotics such as ciprofloxacin can be used against several bacterial diseases. In contrast, antivirals that have similar broad-spectrum properties and treatments that target common disease pathways, such as sepsis, remain targets for development. For a discussion of such countermeasures, see Gigi Gronvall, Jason Matheny, and Bradley Smith, et al., "Flexible Defenses Roundtable Meeting: Promoting the Strategic Innovation of Medical Countermeasures," *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science*, vol. 5, no. 3 (2007), pp. 271-277.

[48] U.S. Department of Health and Human Services, Public Health Emergency Medical Countermeasure Enterprise, "Implementation Plan For Chemical, Biological, Radiological and Nuclear Threats," 72 *Fed. Reg.* 20122, April 23, 2007.